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| SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473 | | | EXAMINER GILLIGAN, CHRISTOPHER L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3626 | |
| DATE MAILED: 12/01/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/784,721 | Applicant(s) HENDERER ET AL. | |
| | Examiner Luke Gilligan | Art Unit 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Applicant's election of claims 1-15 in the reply filed on 9/8/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claim 16-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/8/05.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Barnhill et al., U.S. Patent No. 6,306,087.
5. As per claim 1, Barnhill teaches a networked expert system for automatic evaluation and quality control of medical point of care laboratory measurement data, comprising: a point of care measuring device disposed at a point of care which obtains point of care laboratory measurement data (see column 7, lines 45-49); a central expert system, disposed remote from said location of point of care, and a data link, selected from the group consisting of a data line and a data network, connecting said central expert system to said point of care measuring device (see column 7, lines 62-66); and said central expert system being accessible by a

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treating physician via said data link to function as a virtual laboratory data collection and diagnostic system for acting on said point of care laboratory measurement data to make an evaluation available to said treating physician based on said point of care laboratory measurement data (see column 7, line 66 – column 8, line 16).

6. As per claim 2, Barnhill teaches the system of claim 1 as described above. Barnhill further teaches said point of care measuring device is disposed at a facility of a physician (see column 8, lines 8-10).

7. As per claim 3, Barnhill teaches the system of claim 1 as described above. Barnhill further teaches said expert system is connected online to a central laboratory for automatically reporting back a listing to said treating physician of secondary examinations available for acting on said point of care laboratory measurement data if an initial evaluation at said expert system of said point of care laboratory measurement data does not produce a definitive diagnosis (see column 13, lines 44-60).

8. As per claim 4, Barnhill teaches the system of claim 3 as described above. Barnhill further teaches the central laboratory reports the results of the secondary examinations to the expert system and the expert system re-evaluates the point of care laboratory measurement data by using the results of the secondary examinations (see column 13, lines 44-60).

9. As per claim 5, Barnhill teaches the system of claim 3 as described above. Barnhill further teaches a request to the point of care is automatically made for providing a sample for the central laboratory (see column 13, lines 44-60).

10. As per claim 6, Barnhill teaches the system of claim 1 as described above. Barnhill further teaches a plurality of sub-systems forming said central expert system connected to each other via a data network using data encoding (see column 17, lines 12-23).

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11. As per claim 7, Barnhill teaches the system of claim 1 as described above. Barnhill further teaches said expert system includes a data bank containing up-to-date medical knowledge and patient data and acts on said point of care laboratory measurement data using said medical knowledge and said patient data (see column 19, lines 19-26).

12. As per claim 12, Barnhill teaches a networked expert system for automatic evaluation and quality control of medical point of care laboratory measurement data, comprising: a communications interface for receiving a message including a point of care laboratory measurement data (see column 7, lines 45-49); a central expert system including access to a data bank for examining the point of care laboratory measurement data (see column 7, lines 62-66); a data bank containing up-to-date medical knowledge and patient data (see column 20, lines 42-49); an input processor for receiving data comprising a diagnostic evaluation of the point of care laboratory measurement data and therapy concepts and background knowledge (see column 23, lines 26 – column 34); and a distribution processor for forwarding the received diagnostic evaluation data and therapy concepts and background knowledge to a destination system (see column 7, line 62 – column 8, line 10).

13. Claims 13-15 contain substantially similar additional limitations to those already addressed in claims 2-4 and, as such, are rejected for similar reasons as given above.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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15. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al., U.S. Patent No. 6,306,087 in view of Jachimowicz et al., U.S. Patent No. 5,763,862.

16. As per claim 8, Barnhill teaches the system of claim 6 as described above. Barnhill does not explicitly teach means for limiting access to said up-to-date medical knowledge and patient data only to authorized persons. Jachimowicz teaches means for limiting access to medical information to only authorized persons (see column 3, lines 44-48). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this data security means into the system of Barnhill. One of ordinary skill in the art would have been motivated to incorporate this element for the purpose of enhancing security of sensitive data located at various locations (see column 3, lines 52-59 of Jachimowicz).

17. As per claim 9, Barnhill in view of Jachimowicz teach the system of claim 8 as describe above. Barnhill does not explicitly teach at the location of said treating physician, a chip card reader which requires insertion of a chip card of an authorized user in order to authorize access to said central expert system. Jachimowicz teaches a chip card reader which requires insertion of a chip card of an authorized user in order to authorize access to said central expert system (see column 3, lines 44-48). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this data security means into the system of Barnhill for the reasons given above with respect to claim 8.

18. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnhill et al., U.S. Patent No. 6,306,087 in view of Stevens et al., U.S. Patent No. 6,599,481.

19. As per claim 10, Barnhill teaches the system of claim 1 as described above. Barnhill does not explicitly teach a container for obtaining a patient specimen having an electronically readable identifier thereon. Stevens teaches a container for obtaining a patient specimen

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having an electronically readable identifier thereon (see column 4, lines 1-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Barnhill. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of facilitating more efficient processing of handling operations within a laboratory (see column 4, lines 6-7 of Stevens).

20. As per claim 11, Barnhill in view of Stevens teaches the system of claim 10 as described above. Barnhill does not explicitly teach said electronically readable identifier is a bar code. Stevens further teaches said electronically readable identifier is a bar code (see column 4, lines 1-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Barnhill for the reasons given above with respect to claim 10.

Response to Arguments

21. In the remarks filed 6/14/05, Applicants argue in substance that (1) Barnhill does not teach a central expert system acting on point of care laboratory measurement data to make an evaluation available to the treating physician; (2) Barnhill does not teach reporting back secondary examinations if an initial evaluation does not produce a definitive diagnosis and reevaluating data using the secondary examinations; (3) Barnhill does not teach requesting to provide a sample for the central laboratory; (4) Barnhill does not teach up-to-date medical knowledge; (5) there is not motivation to combine Barnhill with Jachimowicz or with Stevens.

22. In response to Applicants' argument (1), it is respectfully submitted that the Examiner is interpreting the diagnostic evaluation performed by the neural network-based expert system, that can be provided to the treating physician, to be a form of the recited evaluation that is made available by acting of point of care laboratory measurement data. It appears that Applicant is

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arguing that the claimed evaluation provides therapy concepts and background knowledge. It is respectfully submitted that none of the claims recite such a feature. Rather, claim 12 (the only claim in which these two terms appear) recites receiving and forwarding therapy concepts and background knowledge to a destination system. However, the claim makes not mention of how these pieces of information are derived or what data they encompass. Therefore, it is respectfully submitted that information that is provided in addition to a diagnosis, such as underlying causes for osteopenia (see column 23, lines 26-34), is a form of the recited therapy concepts and background knowledge.

23. In response to Applicants' argument (2), it is respectfully submitted that the Examiner is relying on an alternative embodiment of Barnhill in which a two step analysis of the biomarkers is performed. In this embodiment, the diagnostic value obtained by the initial analysis is further analyzed by a set of heuristic rules. This data is then processed to yield a second diagnostic value (see column 19, lines 19-26). Therefore, this Examiner is interpreting the analysis in accordance with the set of heuristic rules to be a form of secondary examination and the second processing of the output data to be a form of re-evaluation. Furthermore, it is noted that such a procedure is used when the initial evaluation is insufficient due to presence of a dominant predictive variable (see column 13, lines 44-60).

24. In response to Applicants' argument (3), it is respectfully submitted that the claims do not define in what form the request for the sample is made (i.e. electronic request, etc.). Therefore, this term has been given the broadest reasonable interpretation to one of ordinary skill in the art given how the term is currently recited in the claim. Since the health care provider is responsible for supplying patient data (see column 7, line 62 – column 8, line 10), it is submitted that by virtue of utilizing the system of Barnhill, the health care provider is requested to provide patient samples for evaluation.

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25. In response to Applicants' argument (4), it is respectfully submitted that neural networks of Barnhill, which are utilized in conjunction with patient data to evaluate the patient, contain up-to-date medical knowledge through the training of the neural networks (see column 19, lines 27-34). Therefore, it is respectfully submitted that the trained neural-networks acting on the point of care laboratory measurement data teach this limitation.

26. In response to Applicants' argument (5), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is respectfully submitted that the Examiner has relied upon suggestions found in the applied prior art in support of the combination as noted in paragraphs 16 and 19 above.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner can normally be reached on Monday-Friday 8am-5:30pm.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


CLG
11/23/05


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